K023454

APR 2 3 2003

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Single-width Airway Module M-miniC and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

October 8, 2002

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ Single-width Airway Module M-miniC and accessories

COMMON NAME:

Carbon dioxide gas monitor

CLASSIFICATION NAME:

The following Class II classification appears applicable:

CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-phase	868.1400

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Single-width Airway Module M-miniC and accessories is substantially equivalent in safety and effectiveness to the legally marketed predicate M-CAIOVX module (K001814).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The M-miniC is used in the Datex-Ohmeda S/5 modular family which consists of four different types of monitors: Anesthesia Monitor, Compact Anesthesia Monitor, Critical Care Monitor and Compact Critical Care Monitor. An monitor consists of four basic elements: display, keyboard, Central unit and modules. The display shows up to eight waveforms, real-time data and trends. With keyboard you can control the monitor. The keyboard consists of membrane keys and a comwheel. By pushing a key you can open a menu in which you can move by turning the comwheel.

The M-miniC module consists of miniCO2 infrared measuring sensor for measuring CO2. It is assembled in a Single-width module, which occupies one slot in a Datex-Ohmeda S/5 modular monitor frame. The main accessories include airway gas sampling lines, mini D-fend water traps and airway adapters The module is first plugged into the frame of the monitor. The sampling line is attached to the module connector. The monitor is switched on and the gas sampling line is attached to the airway adapter. The airway adapter is attached between ventilator Y-piece and Heat and moisture exchanger (HME) of the patient's intubation tube. The monitor displays measurements from the M-miniC module in the form of numeric values, curve and trends. The monitor also generates audible and visual alarms for this module and indicates the priorities and sources of alarms.

INTENDED USE as required by 807.92(a)(5)

Intended use:

The Datex-Ohmeda S/5 Single-width airway module, M-miniC is intended to be used with Datex-Ohmeda S/5 modular monitors; S/5 Anesthesia Monitor, S/5 Compact Anesthesia Monitor, S/5 Critical Care Monitor and S/5 Compact Critical Care Monitor for monitoring CO2 and respiration.

Indications for use:

The Datex-Ohmeda S/5 Single-width airway module, M-miniC and accessories is indicated for monitoring CO2 and respiration rate of all hospital patients. M-miniC is indicated for monitoring patients weighing more than 5kg (11 lbs.). The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The M-miniC module is substantially equivalent in safety and effectiveness to the predicate M-CAIOVX module (K001814). Both the M-miniC and predicate can be used with the same Datex-Ohmeda modular monitors, S/5 Anesthesia Monitor, S/5 Critical Care Monitor, S/5 Compact Anesthesia monitor and S/5 Compact Critical Care Monitor. The M-miniC is compatible with monitor main software L-ANE02(A), L-CANE02(A), L-ICU02(A) and L-CICU02(A) and newer while the predicate (because it was released previously) is compatible with S-ANE97, S-ARK97 and S-ICU97 monitor main software and newer. The measurement principle of CO2 is the same for both the M-miniC and predicate M-CAIOVX modules. They are side stream gas analyzers, measuring real time concentrations of CO2. They measure absorbtion of CO2 at 4.2-4.3µm using narrow band IR filters. The detectors of both sensors are thermopiles. The principal structure of the CO2 sensors is the same; there is an IR source, a thermal insulator, a sample chamber and a detector. The sample chamber and detector are inside an aluminium frame and that frame has a thermal insulator around it. The IR source is constant current controlled.
The main difference is that the M-miniC measures only CO2 while the predicate M-CAIOVX measures additionally N2O and anesthetic agents and therefore the CO2 sensor of the M-miniC is smaller and consumes less power. The predicate M-CAIOVX also has a separate paramagnetic

sensor which measures Oxygen and a separate spirometry unit which monitors patient ventilation and a gas exchange measurement. Both the M-miniC and predicate M-CAIOVX fulfill the same electrical safety standard IEC 601-1. Software in the M-miniC module is based on the same principles as the software of the predicate M-CAIOVX. It is simpler because it has only one gas measurement channel. Its basic functions such as CO2 concentration calculation, pump and IR source control are the same. Its communication protocol with the monitor is also the same. The M-miniC uses the same type of CO2 accessories as the predicate M-CAIOVX. The M-CAIOVX also has many accessories that are not used with the M-miniC because the M-miniC only uses accessories associated with CO2 monitoring. The M-miniC and predicate M-CAIOVX CO2 monitoring accessories are identical except for a new 6 m sampling line and the new mini D-fend water trap. The 6 m sampling line is just a longer version of the 2 m/3 m sampling lines of the predicate and is made from identical materials. The new mini D-fend is a smaller version of the predicate D-fend. The operation principle is the same. The M-miniC module is a single width module while the predicate M-CAIOVX is a double width module. This means the M-miniC module only takes up one slot in the monitor frame. The CO2 measurement range of the M-miniC is from 0 to 20 vol% while the CO2 measurement range of the predicate M-CAIOVX is from 0 to 15 vol%. The warm-up time of the M-miniC is 1 min while the warm-up time of the predicate M-CAIOVX is 2 min. The sample flow of the M-miniC is 150 ml/min while the sample flow of the predicate M-CAIOVX is 200 ml/min. The CO2 rise time of the M-miniC is < 300 ms while the CO2 rise time of the predicate M-CAIOVX is < 400 ms. The environmental specification for both modules is the same.

Based on the above analysis and other documentation included in this 510(k) notification and attachments, it is evident that the main features and indications for use of the Datex-Ohmeda S/5 Single-width Airway Module M-miniC and accessories are substantially equivalent to the predicate Datex-Ohmeda Compact Airway Module M-CAiOVX (K001814). The comparison above as well as supporting data and analysis shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5 Single-width Airway Module M-miniC and accessories.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ Single-width Airway Module M-miniC and accessories complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- IEC 60601-1:1988+Amdt 1:1991+Amdt 2:1995
- EN 60601-1: 1990+A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No. 601.1-M90 +S1:1994+Amdt2:1998
- IEC 60601-1-2:1993
- EN 60601-1-2:1993
- IEC 60601-1-4:1996+Amdt 1:1999
- EN 60601-1-4:1996+Amdt A1:1999
- ISO 9918:1993 / EN 864:1996
- ASTM F-1456 (1992)
- UL 2601:1997

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Single-width Airway Module M-miniC and accessories as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2003

Joel C. Kent
Manager, Quality and Regulatory Affairs
Datex-Ohmeda
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K023454
Trade/Device Name: Datex-Ohmeda S/5 Single-width Airway module M-miniC and accessories
Regulation Number: 868.1400
Regulation Name: Carbon-Dioxide Gas Analyzer, Gaseous-Phase
Regulatory Class: II
Product Code: CCK
Dated: January 22, 2003
Received: January 23, 2003

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023454

Device Name: **Datex-Ohmeda S/5 Single-width airway module, M-MINIC and accessories**

The Datex-Ohmeda S/5 Single-width airway module, M-miniC and accessories is indicated for monitoring CO2 and respiration rate of all hospital patients. M-miniC is indicated for monitoring patients weighing more than 5kg (11 lbs.).

The device is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023454